



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Marc Feldmann, Ravinder N. Maini and

Richard O. Williams

Serial No. : 10/762,096

Filed: January 20, 2004.

FOR : TREATMENT OF TUMOR NECROSIS FACTOR-MEDIATED

DISEASES

1185 Avenue of the Americas New York, New York 10036

February 17, 2005

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents which are listed on the attached Form PTO-1449 (EXHIBIT A). Copies of the documents listed below as items 7 and 8 are attached hereto as EXHIBITS 1 and 2:

- U.S. Patent No. 5,741,488, issued April 21, 1998 (Feldmann, et al.);
- 2. U.S. Patent No. 6,270,766, issued August 7, 2001 (Feldmann, et al.);
- U.S. Patent No. 6,770,279, issued August 3, 2004 (Feldmann, et al.);

Applicants: Marc Feldmann et al.

Serial No. : 10/762,096

Filed: January 20, 2004

Page 2

4. U.S. Patent Application Publication No. 2002/0010180 A1, published January 24, 2002;

- 5. U.S. Patent Application Publication No. 2002/0068057 A1, published June 6, 2002;
- 6. U.S. Patent Application Publication No. US 2002/0136723 A1, published September 26, 2002;
- 7. St. Clair, E. W., et al., "Combination of Infliximab and Methotrexate Therapy for Early Rheumatoid Arthritis", <a href="Arthritis & Rheumatism">Arthritis & Rheumatism</a>, 50(11);3432-3443 (2004) (EXHIBIT 1); and
- 8. Klareskog, L., et al., "Therapeutic effect of the combination of etanercept and methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomized controlled trial", <a href="The Lancet">The Lancet</a>, 363:675-681 (2004) (EXHIBIT 2).

Because the above-identified application was filed after June 30, 2003, copies of the U.S. Patents and Patent Application Publications listed as items 1-6 are not required and are not provided.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Applicants : Marc Feldmann et al.

Serial No.: 10/762,096

Filed: January 20, 2004

Page 3

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissióner for Patents P.Ø. BØX 1450

Alexandria, VA 22313-1450

Alan J. Morrison Reg. No. 37,399

J. Morrison Date

Respectfully submitted,

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicant
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036

(212) 278-0400

Form PTO-1449		449 U.S. Dep	U.S. Department of Commerce			Application Number	10/762,096			
			nd Trademark-Office		Filing Date	January 20, 2004				
				OIPE		First Named Inventor	Marc Feldmann			
INFORM	MAT	TION DISCLOSURE STAT	ГЕМГ	E <b>X</b> T	SCI	Art Unit				
Use sev	eral :	sheets if necessary)		FEB 2	2 2005 =	Examiner Name				
				J.S. PATENT STAPE		Attorney Docket No.	1455/65019-CA-2 PCT-US/JPW/AJ			
<del> </del>		7	<u>U.S. P</u> /	ATENT BEAR	PHENTS					
Examiner Initials*	Cite No.1	No. Number-Kind Code <sup>2 (if known)</sup>		Date I-DD-YYYY	Name of Patentee or Applicant of Cited Document					
		US-5741488	ļ	04-21-1998 Feldmann 08-07-2001 Feldmann		Feldmann, et al.				
	[ '	US-6270766	08-07			, et al.				
		US-6770279			Feldmann, et al.					
		US-20020010180-A1			Feldmann, et al.					
	US-20020068057-A1		06-06-2002		Feldmann, et al.					
	US-20020136723-A1		09-26-2002		Feldmann, et al.			•		
				<u> </u>		,				
								-		
·										
				· · · · · · · · · · · · · · · · · · ·			<del></del>			
			1		<del></del>					
<del></del> -				PATENT D			l'and CC'4 I			
Examiner Initials*	Cite No.1	Foreign Patent Document Country Number <sup>4</sup> -Kind Code <sup>5 (if known</sup>	Code <sup>3-</sup>	Publicati Date MM-DD-YY		Name of Patentee or App Document		T <sup>6</sup>		
	<u> </u>									
	<u> </u>									
	<u> </u>									
	<u> </u>									
_						·				
								<u> </u>		
	<u> </u>							<u> </u>		
EXAMINER				DATE CONSI	DERED			i		
SIGNATUR	E			1			<del></del>			

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds of Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

Applicants: Marc Feldmann et al. Serial No.: 10/762,096

Filed: January 20, 2004

Exhibit A

Form PT	O-144	U.S. De	partment of Comm	erce	Application Number	10/762,096					
		Patent :	and Trademark Bf	fice .	Filing Date	January 20, 20	04				
			/0		First Named Inventor	Marc Feldman	n				
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)  Art Unit  Examiner Name  Attorney Declar No. 1455/6501											
(Use severa											
			\F1	£/	Attorney Docket No.	1455/65019-C					
			THAT	EMAH		PCT-US/JPW/	AJM/CY				
т		NON F	ATENT LITERAT	URE DOC	UMENTS .						
Examiner Initials	No. item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(spublisher, city and/or country where published.										
	ST. CLAIR, E. W., et al., "Combination of Infliximab and Methotrexate Therapy for										
		Early Rheumatoid A	Arthritis", <u>Arthritis &amp;</u>	Rheumatisi	<u>m</u> , 50(11):3432-344	3 (2004)					
	KLARESKOG, L., et al., "Therapeutic effect of the combination of etanercept and										
	methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomised controlled trial", <u>The Lancet</u> , 363:675-681 (2004)										
EXAMINE	R		DATE CONSIDERED			<del></del>					

<sup>\*</sup>EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a checkmark here if English language Translation is attached.